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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,763	09/26/2003	David J. Yang	UTSC:664USC1	1049

32425 7590 06/03/2005

FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,763

Applicant(s)

YANG ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/26/03; 4/9, 12/23, & 6/1/04; 2/7/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-58, 61-64, 66, 67, 69, 70 and 79 is/are rejected.
- 7) ☒ Claim(s) 59, 60, 65, 68, 71-78 and 80-82 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/7/05, 6/1/04, & 4/9/04

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

PS

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the following: (a) the amendment filed 12/23/04 wherein the specification was amended and (b) the amendment filed 9/26/03 wherein the specification was amended; claims 1-51 were canceled; and claims 52-82 were added.

Note: Claims 52-82 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to a method of imaging having the steps as set forth in independent claim 52.

102 REJECTIONS

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 52, 53, 55, 56, 58, 61-67, 69, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (The Journal of Nuclear Medicine, May 1995, Vol. 36, No. 5, pages 850-858).

Anderson et al disclose the preparation, biodistribution, and dosimetry of coupper-64-labeled anti-colorectal carcinoma monoclonal antibody fragments 1A3-F(ab')₂. The specific species of interest is 64C-labeled BAT –2iminothiolane-1A3-

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Fab')₂ wherein the linking agent is 2-iminothiolane (2IT). The biodistribution of the 64-Cu-labeled complex was determined in rats and tumor bearing hamster. PET imaging was also determined (see entire document, especially, abstract; page 856, Table 3; pages 857-858, Conclusion). Thus, both Applicant and Anderson et al disclose a method of imaging a site within a subject by administering an effective amount of a composition comprising a radionuclide labeled bisaminoethanethiol (BAT) targeting ligand complex and analyzing the radioactive signal by emission tomography.

5. Claims 52, 53, 55, 56, 58, 61-64, 66, 67, 69, 70, and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (The Journal of Nuclear Medicine, 1992, Vol. 33, No. 9, pages 1685-1691).

Anderson et al disclose copper-64 labeled antibodies useful for PET imaging. In particular, the species of interest are 64Cu- or 67Cu-benzylTETA-1A3 and 64Cu- or 67Cu-benzyl-TETA-1A3-F(ab')₂. The species are analyzed using positron emission tomography (see entire document, especially, abstract; page 1686 'Materials and Methods'). The entire tumor, bladder, heart, stomach, kidneys, spleen, and thyroid were removed from the subject and analyzed (page 1687, 'Animal Model'). Thus, both Applicant and Anderson et al disclose a method of imaging a site within a subject by administering an effective amount of a composition comprising a radionuclide labeled bisaminoethanethiol targeting ligand complex and analyzing the radioactive signal by emission tomography.

Note: It should be noted that TETA is another name for BAT.

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103 REJECTIONS

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 52, 54, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (The Journal of Nuclear Medicine, May 1995, Vol. 36, No. 5, pages 850-858) in view of Anderson et al (The Journal of Nuclear Medicine, 1992, Vol. 33, No. 9, pages 1685-1691).

Anderson et al (the primary reference) fail to disclose that SPECT is another possible method for analyzing the emission tomography of the labeled copper complex. In addition, Anderson et al fail to disclose other possible mammals that may be used in their experiment.

Anderson et al (the secondary reference) disclose copper-64 labeled antibodies useful for PET imaging. In particular, the species of interest are ^{64}Cu - or ^{67}Cu -benzylTETA-1A3 and ^{64}Cu - or ^{67}Cu -benzyl-TETA-1A3-F(ab')₂. The species are analyzed using positron emission tomography (see entire document, especially, abstract; page 1686 'Materials and Methods'). The entire tumor, bladder, heart, stomach, kidneys, spleen, and thyroid were removed from the subject and analyzed (page 1687, 'Animal Model'). In addition, it is disclosed that ^{64}Cu may be used for PET and SPECT analysis (page 1691, first incomplete paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the primary Anderson et al reference using the teachings of the secondary reference and imaging as set forth in independent claim 52 because (1) a skilled practitioner in the art would recognize that the labeled complexes are useful for both PET and SPECT imaging since the secondary reference discloses that SPECT imaging is possible and the actual primary and secondary references themselves disclose using the copper labeled complexes for PET imaging (see page 1691, first incomplete paragraph). (2) It would have been obvious to a skilled practitioner in the art to use the labeled complexes for humans since both the primary and secondary references disclose that the copper-labeled complexes would be suitable for PET imaging of colorectal cancer in patients and disclose its use with a mammal (i.e., a rat). Thus, interchanging one mammal with another would be expected to yield similar biodistribution results. Since both references disclose the use of labeled copper complexes for PET imaging, the references may be considered to be within the same field of endeavor; hence, their teachings are combinable.

8. Claims 52, 54, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (The Journal of Nuclear Medicine, 1992, Vol. 33, No. 9, pages 1685-1691).

Anderson et al fail to disclose that SPECT is another possible method for analyzing the emission tomography of the labeled copper complex. Also, Anderson et al fail to disclose other possible mammals that may be used with their invention.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the labeled complex for SPECT analysis (see page 1691, first incomplete paragraph). In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the labeled complexes for humans because Anderson et al disclose that the copper labeled complexes are suitable for PET imaging of colorectal cancer in patients and disclose the use of the labeled complex with a mammal (i.e., a rat). Thus, interchanging one mammal with another would be expected to yield similar biodistribution results.

CLAIM OBJECTIONS

9. Claims 59, 60, 65, 68, 71-78, and 80-82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Note: The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the additional limitations present in the dependent claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1616

May 31, 2005